DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 7, 2015

Maquet Cardiopulmonary AG
% Whitney Torning
Director, Regulatory Affairs
Maquet Cardiovascular
45 Barbour Pond Drive
Wayne, New Jersey 07470

Re: K150267
Trade/Device Name: QUADROX-i Adult Oxygenator with and without integrated Arterial Filter
QUADROX-i Small Adult Oxygenator with and without integrated Arterial Filter
QUADROX-iD Adult Oxygenator
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ, DTR, DTM
Dated: March 6, 2015
Received: March 9, 2015

Dear Whitney Torning:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K150267

Device Name: QUADROX-i Adult Oxygenator with and without integrated Arterial Filter

Intended Use:

The membrane oxygenator QUADROX-i Adult is intended for use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery.
The blood flow rate is defined from 0.5 – 7 l/min.
Within the specified flow rate range, the device oxygenates the blood, eliminates carbon dioxide from the blood and regulates blood temperature.
The QUADROX-i Adult (HMO 71000) version with integrated arterial filter also filters out air bubbles and particles larger than 40 µm.
The device's utilization period is limited to six hours.
Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K150267

Device Name: QUADROX-i Small Adult Oxygenator with and without integrated Arterial Filter

Intended Use:

The membrane oxygenator QUADROX-i Small Adult is intended for use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery.
The blood flow rate is defined from 0.5 – 5 l/min.
Within the specified flow rate range, the device oxygenates the blood, eliminates carbon dioxide from the blood and regulates blood temperature.
The QUADROX-i Small Adult (HMO 51000) version with integrated arterial filter also filters out air bubbles and particles larger than 40 µm.
The device's utilization period is limited to six hours.
Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K150267

Device Name: QUADROX-iD Adult Oxygenator

Intended Use:

The membrane oxygenator QUADROX-iD Adult is intended for use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery.
The blood flow rate is defined from 0.5 - 7 l/min.
Within the specified flow rate range, the device oxygenates the blood, eliminates carbon dioxide from the blood and regulates the blood temperature.
The device's utilization period is limited to six hours.
Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Prepared in accordance with 21 CFR Part 807.92

GENERAL INFORMATION

Submitter's name and address**:** MAQUET Cardiopulmonary AG
Kehler Straße 31
D-76437 Rastatt
Germany

Contact person and telephone number**:**

Whitney Törning
Director, Regulatory Affairs
MAQUET Cardiovascular
45 Barbour Pond Drive
Wayne, NJ 07470
USA

Phone: 973-709-7994
Fax: 973-807-9210
Email: whitney.torning@maquet.com
Date prepared: February 3, 2015

DEVICE INFORMATION:

Trade Name: QUADROX-i Adult / Small Adult Oxygenators
QUADROX-iD Adult Oxygenators,

Common/Generic Name: Oxygenator with and without integrated arterial filter

Classification Name: Oxygenator, cardiopulmonary bypass, heat exchanger, cardiopulmonary bypass, filter, blood cardiopulmonary bypass, arterial line

Main product code:
Code of Federal Regulations: 21 CFR 870.4350
Product Code: DTZ

Sub product codes:
Code of Federal Regulations: 21 CFR 870.4240
Product Code: DTR

(only applicable for QUADROX-i Adult / Small Adult Oxygenators with integrated arterial filter):

Code of Federal Regulations:	21 CFR 870.4260
Product Code:	DTM

PREDICATE DEVICE INFORMATION:

The modified QUADROX-i Adult / Small Adult and QUADROX-iD Adult Oxygenators are substantially equivalent in function and intended use to predicate QUADROX-i Adult / Small Adult with Holding Clamp and QUADROX-iD Adult with Holding Clamp (K132829).

DEVICE DESCRIPTION:

The QUADROX-i Small Adult / Adult and QUADROX-iD Adult oxygenators are blood-gas exchangers with integrated heat exchanger and optionally integrated arterial blood filter (only available for QUADROX-I Small Adult / Adult). They are used in cardiac surgery, in combination with a heart-lung machine, to oxygenate blood, remove carbon dioxide and adjust blood temperature.
The integrated arterial filter is intended to filter out air bubbles and particles larger than 40µm. It is used for removing gaseous embolisms and aggregates from blood components from the arterial blood during extracorporeal circulation. It is a screen filter with pre-post-de-airing mechanic.

INDICATIONS FOR USE:

QUADROX-i Adult Microporous Membrane Oxygenator with and without integrated Arterial Filter

The membrane oxygenator QUADROX-i Adult is intended for use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery.
The blood flow rate is defined from 0.5 – 7 l/min.
Within the specified flow rate range, the device oxygenates the blood, eliminates carbon dioxide from the blood and regulates blood temperature.
The QUADROX-i Adult (HMO 71000) version with integrated arterial filter also filters out air bubbles and particles larger than 40 µm.
The device's utilization period is limited to six hours.
Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

QUADROX-i Small Adult Microporous Membrane Oxygenator with and without integrated Arterial Filter

The membrane oxygenator QUADROX-i Small Adult is intended for use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery.
The blood flow rate is defined from 0.5 – 5 l/min.
Within the specified flow rate range, the device oxygenates the blood, eliminates carbon dioxide from the blood and regulates blood temperature.
The QUADROX-i Small Adult (HMO 51000) version with integrated arterial filter also filters out air bubbles and particles larger than 40 µm.
The device's utilization period is limited to six hours.
Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

QUADROX-iD Adult Diffusion Membrane Oxygenator

The membrane oxygenator QUADROX-iD Adult is intended for use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery.
The blood flow rate is defined from 0.5 - 7 l/min.
Within the specified flow rate range, the device oxygenates the blood, eliminates carbon dioxide from the blood and regulates the blood temperature.
The device's utilization period is limited to six hours.
Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATES:

The modified QUADROX-i Adult / Small Adult and QUADROX-iD Adult Oxygenators are substantially equivalent to the predicate QUADROX-i Adult / Small Adult with Holding Clamp and QUADROX-iD Adult with Holding Clamp (K132829). The modification essentially consists of modifying the blood inlet and outlet side from an exclusively glued connection to a combined connection of gluing and screwing. The reason of the redesign of the bonding between housing and blood inlet / outlet connectors is to replace the Holding Clamp.

NON-CLINICAL TESTS:

Performance testing has resulted in data that demonstrates that the modified QUADROX-i Adult / Small Adult and QUADROX-iD Adult Oxygenators perform within its specifications and within the acceptable limits of the applied performance standards. The following performance characteristics of the modified QUADROX-i Adult / Small Adult and QUADROX-iD Adult Oxygenators were extensively compared with the predicate devices to determine substantial equivalence:

- Stability
- Stability axial
- Crash test
- Blood Cell Damage
- Blood side integrity
- Heat exchanger side integrity
- Sterile packaging integrity

CLINICAL TESTS:

No clinical evaluation of the modified device was conducted or required.

CONCLUSION:

Based upon the information submitted in this Special 510(k) premarket notification, MAQUET Cardiopulmonary's modified QUADROX-i Adult / Small Adult and QUADROX-iD Adult Oxygenators are substantially equivalent to the currently marketed QUADROX-i Adult / Small Adult with Holding Clamp and QUADROX-iD Adult with Holding Clamp (K132829). The modified Oxygenators are similar to the predicate device in the intended use, the fundamental scientific technology of the device, and do not raise new issues of safety and effectiveness.